In the United States Court of Federal Claims office of special masters

No. 19-1570V UNPUBLISHED

VANESSA MORRIS.

Petitioner.

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: December 15, 2021

Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu); Shoulder Injury Related to Vaccine Administration (SIRVA); Table Claim Dismissal.

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Benjamin P. Warder, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM¹

On October 9, 2019, Vanessa Morris filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that as a result of an influenza ("flu") vaccine received on October 4, 2017, she suffered a shoulder injury related to vaccination ("SIRVA") as defined on the Vaccine Injury Table (the "Table"). Petition (ECF No. 1) at Preamble. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the opinion will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that Petitioner's Table SIRVA claim must be dismissed, because the evidentiary record does not support the conclusion that the requisite onset of her pain occurred within 48 hours following administration of the flu vaccine.

I. Relevant Procedural History

The Petition and supporting documentation were deemed to be sufficiently complete, and the matter was assigned to the SPU in October 2019. On January 12, 2021, Respondent completed his formal medical review of the case and invited litigative risk settlement discussions. ECF No. 20. Petitioner thereafter transmitted a settlement demand and supporting documentation on April 12, 2021. ECF No. 22.³ Respondent provided an offer on May 6, 2021, but the parties reached an impasse in their negotiations. ECF No. 23.

On August 24, 2021, Respondent filed his Rule 4(c) Report contending that Petitioner had not established onset within 48 hours of vaccination, as required for a Table SIRVA. Respondent argued that within the medical records, Petitioner provided an incorrect date of vaccination on multiple occasions,⁴ and that she also provided inconsistent information regarding the onset of her left shoulder pain. Rule 4(c) Report (ECF No. 26) at 14.

I then directed the parties to file briefs and any other evidence that would assist my resolution of the disputed issues. ECF No. 27. Petitioner filed a motion for a ruling on the record on October 6, 2021, ECF No. 28, to which Respondent filed a response on October 15, 2021, ECF No. 29. Petitioner did not file a reply. This matter is now ripe for adjudication.

II. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment,

³ The case does not involve a workers' compensation claim or a Medicaid lien. ECF No. 10. Petitioner initially reported that she was seeking an award for pain and suffering, out of pocket expenses, and lost wages She suggested that her lost wages were "complex" and required an expert economist (which request I deferred during the parties' litigative risk settlement discussions). ECF Nos. 19-21.

⁴ However, Respondent recognized that there was preponderant evidence that Petitioner did receive the subject flu vaccine on October 4, 2017; that the vaccine was administered in her left deltoid, as alleged; and that the vaccine was intended for intramuscular administration. Rule 4(c) Report at 2; n. 2-3.

test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19. And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] ... did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

III. Relevant Factual Evidence

I have fully reviewed the evidence pertaining to the onset question, including all medical records, Respondent's Rule 4(c) Report, and the parties' briefs.⁵ find most relevant the following:

- Upon receiving the subject vaccination, Ms. Morris was 58 years old. She was generally healthy, with no history of problems with her left shoulder. See, e.g., Ex. 2 at 22-26, 161-99; Ex. 7 at 3-9; Ex. 9 at 7-62; Ex. 10 at 7-78.
- Petitioner was employed by Blue Cross Blue Shield in Arkansas. See, e.g., Ex. 4 at 6, 33; Ex. 5 at 52 (Petitioner's self-identification as a "specialist").
- On October 4, 2017, a registered nurse administered the subject flu vaccine, which was intended for intramuscular administration, to Petitioner's left deltoid. Ex. 1 at 1; Rule 4(c) Report at 2, n. 2-3.
- While the vaccine record is from Freiderica Pharmacy & Compounding, Petitioner and a coworker recall that the vaccines were administered at their workplace's breakroom. Exs. 13-14.

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⁵ I recognize that Petitioner submitted two affidavits herself, as well as one from a coworker with recollections concerning the circumstances of their vaccinations in the workplace. Exs. 11, 13-14. These affidavits do not address the onset of Petitioner's shoulder pain, however.

- On November 8, 2017, Petitioner left a message for her primary care practice. Shawn Fells recorded that "since [Petitioner] received the flu shot in late October," she had been experiencing pain at the injection site and difficulty moving her arm, and that she had taken Tylenol and Ibuprofen with no relief. Ex. 2 at 20.
- The following day, November 9, 2017, a different individual, Nurse Jill Ashley, returned the call. Nurse Ashley memorialized in the record pertaining to this contact that Petitioner "had no pain in her arm for 2 days after her flu shot, but after the 2 days she has had a lot of pain..." Ex. 2 at 20 (emphasis added). Nurse Ashley also recorded that Petitioner had "read online that people have experienced this after the flu shot" and "discussed [that Petitioner's pain] may or may not be related to inj." Id. Nurse Ashley scheduled an appointment for the following Wednesday, November 15, 2017, for the primary care doctor, Rhodora Rhagavan, M.D., to assess Petitioner's shoulder and discuss treatment options. Id.
- At the November 15, 2017, appointment, Dr. Rhagavan recorded Petitioner's history of "pain in her left arm from flu shot x6 weeks," despite the application of ice, heat, electronic stimulation, and ibuprofen. Ex. 2 at 18. Dr. Rhagavan observed that Petitioner had restricted range of motion due to pain. *Id.* Dr. Rhagavan recorded that Petitioner's left arm pain was a "vaccine reaction," and referred her to physical therapy. *Id.*
- Upon starting physical therapy on December 12, 2017, Petitioner reported "left upper arm and shoulder pain that began on October 11th after getting her flu shot." Ex. 3 at 153.
- Petitioner's initial course of physical therapy consisted of nine visits. Ex. 3 at 153-81.⁶ On January 14, 2018, she self-discharged, planning to follow up with Dr. Rhagavan for additional testing and treatment options. *Id.* at 180-81.
- On January 24, 2018, Petitioner followed up with Dr. Raghavan for continued pain in her left arm, which "started of [sic?] after receiving a flu vaccination in that arm," and had been present "for about 4 months now." Ex. 2 at 16. Petitioner's left arm "hurt more than before" despite the non-steroidal anti-inflammatory medications ("NSAIDS") and physical therapy. *Id.* Dr. Raghavan recorded that Petitioner's pain was "chronic," ordered an ultrasound, administered a Toradol injection, and prescribed Tramadol oral pain medications. *Id.*

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⁶ The physical therapy sessions are out of order, but numbered, within Exhibit 5. The sessions were on December 12th, 14th, 19th, 21st, 27th, and 28th, 2017; and January 2nd, 4th, and 9th, 2018.

- Dr. Raghavan referred Petitioner to a neurologist on January 25th, and prescribed gabapentin as a further intervention for her pain on February 1st, 2018. Ex. 2 at 14-15.
- At their February 6, 2018, initial consult, the neurologist Julia McCoy, M.D., recorded:

"[Petitioner] was in good health until October 11th, when she received a standard influenza injection at a local pharmacy. An IM injection in the left deltoid produced no immediate pain or significant change until the next day when the patient 'developed sharp pains' notably over the left deltoid with progressive pain in the proximal arm with pain on range of motion. The patient was given anti-inflammatories which did take the edge off and was given physical therapy for nine weeks which was not beneficial."

Ex. 2 at 155. Dr. McCoy's impression was "influenza injection-induced adhesive capsulitis." *Id.* at 155-57. An EMG nerve conduction study found no evidence for Parsonage-Turner syndrome. *Id.* at 157-60. Dr. McCoy recommended an MRI of the left shoulder and further evaluation by orthopedist Martin Siems, M.D. *Id.* at 157.

- On February 22, 2018, at their initial consult, Dr. Siems recorded that Petitioner had left shoulder pain "since she received a flu shot this year." Ex. 5 at 26. Petitioner's pain and stiffness had persisted despite "nine weeks of physical therapy." Id. Dr. Siems ordered an MRI to confirm his assessment of adhesive capsulitis and to rule out a rotator cuff tear. Id.
- The February 28, 2018, MRI did not identify a rotator cuff tear or tendinopathy. The findings were consistent with adhesive capsulitis, mild acromioclavicular arthrosis, and minimal subacromial and subdeltoid bursitis. Ex. 5 at 57-58.
- On March 12, 2018, Dr. Siems manipulated Petitioner's left shoulder under anesthesia. Ex. 6 at 5; see also Ex. 5 at 21-25 (related medical appointments).
- Later that day, Petitioner began treatment with a new physical therapist for the treatment of "adhesive capsulitis sustained as a result of receiving the flu shot 5 months ago." Ex. 3 at 106. She ultimately underwent 40 physical therapy sessions through October 10, 2018. *Id.* at 20-152.
- On July 3, 2018, orthopedic surgeon Jonathan Wyatt, M.D., met with Petitioner to discuss her left shoulder pain (recorded as being present for "several months,") and plans for further surgical intervention. Ex. 5 at 15-17.
- On August 3, 2018, Dr. Wyatt performed a left shoulder arthroscopy with capsular release, biceps tenotomy with limited debridement, subacromial decompression, and further manipulation of the left shoulder under anesthesia.

Ex. 5 at 39-41; see also id. at 8-15 and Ex. 12 at 16-18 (follow up appointments with Dr. Wyatt).

 At their last known follow-up appointment on June 25, 2019, Dr. Wyatt recorded that Petitioner's left shoulder had improved following surgery and physical therapy, but she had continued pain and limitations in range of motion. She would continue with NSAIDs, topical treatments, and stretching exercises, and would follow up with Dr. Wyatt as needed. Ex. 12 at 15-16.

IV. Findings of Fact

I acknowledge that the standard applied to resolving onset for an alleged SIRVA is liberal, and will often permit a determination in a petitioner's favor, especially in the *absence* of fairly contemporaneous and direct statements within the petitioner's medical records to the contrary. However, not every case can be so preponderantly established. Ultimately, the resolution of such fact issues involves weighing different items of evidence against the overall record.

Here, Petitioner's post-vaccination onset claims (which do eventually tend to report immediate pain) are offset against a record created very near-in-time to vaccination – and this record does not support Petitioner's claim. Specifically, the second post-vaccination record - from the November 9, 2017, telephone encounter with Nurse Ashley - specifically refutes the existence of pain for the first two days after vaccination, placing onset instead at "after the two days." Ex. 2 at 20. The record from the day immediately before (the first record reporting pain) vaguely references pain "since" the receipt of the vaccine – and although this is not inconsistent with an allegation of immediate pain, it is also consistent with the second record, which identifies a particular, later onset. *Id.*

Thereafter, on November 15, 2017, Petitioner reported a six-week history of shoulder pain, which dates back precisely to October 4, 2017. Ex. 2 at 18. However, that record does not mention the vaccination, and could represent a more approximate timeframe. *Compare*, e.g., Ex. 2 at 16 (January 24, 2018, history of shoulder pain "for about 4 months now," which would relate back to before vaccination). Other records contain a history of shoulder pain either "since" or beginning within the first two days after vaccination. However, these were generally created later in time, and contain other inconsistencies. *See*, e.g., Ex. 2 at 20 (dating vaccination in "late" October); Ex. 3 at 153 (providing that the vaccination occurred on October 11th); Ex. 2 at 155 (providing the same incorrect date, and that the vaccination occurred "at a local pharmacy" rather than at Petitioner's workplace).

Overall, the most contemporaneous and specific record was that created by Nurse Ashley, which provides that onset occurred beyond 48 hours after vaccination. Petitioner has provided me no reason not to conclude that this medical record is correct, and she has not provided "consistent, clear, cogent, and compelling" testimony – or other evidence – in rebuttal. *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing Blutstein v. Sec'y of Health & Human Servs., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). And while other records are consistent with post-vaccination pain, they do not merit more weight than a specific and far closer-in-time record. Accordingly, there is not preponderance evidence of onset within 48 hours. 42 C.F.R. § 100.3(a)(I)(C).

Nevertheless, the record *does* support onset having occurred shortly after vaccination – e.g., within the first 72 hours – and seemingly, all other criteria for a Table SIRVA claim. Therefore, Petitioner very likely has a viable non-Table claim. To that end, I urge the parties to make one final brief attempt at settlement – as I would anticipate that even after transfer, Petitioner's claim could prove meritorious despite her inability to meet one Table element.

Conclusion

Petitioner has not preponderantly established that the onset of her shoulder pain occurred within 48 hours of vaccination. Accordingly, Petitioner's Table SIRVA claim is dismissed. Petitioner shall file a joint status report addressing her conveyance of a revised settlement demand for her off-Table claim, and the parties' efforts towards informal resolution, by no later than <u>Friday</u>, <u>January 14</u>, <u>2022</u>. If the parties do not report progress in their efforts, the matter will likely be transferred out of the SPU.

IT IS SO ORDERED.

s/Brian H. Corcoran Brian H. Corcoran Chief Special Master